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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/522,914
Filing Date: January 28, 2005
Appellant(s): GRESHAM, RICHARD D.

Justin J. Ripley
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 19th, 2010 appealing from the Office action mailed August 17th, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

1, 2, 6-26 and 30-33

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 5,665,073	BULOW et al.	9-1997
US 2003/0139767	JESPERSEN	7-2003
US 5,318,221	GREEN et al.	6-1994
US 6,024,741	WILLIAMSON et al.	2-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2 and 6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bulow et al. (US 5,665,073).

Regarding claims 1, 2 and 13, Bulow et al. disclose a surgical instrument comprising: a body portion, 32/36, 42/46, and/or 52/56; a tool member, 38, 48 and/or 58, supported on the distal end of the body portion; and a liquid impermeable elongated cover 12 (col. 5, lines 30-31) supported about the body portion of the instrument, the elongated cover being formed from a collapsible material and having a substantially tubular configuration having open proximal and distal ends, the elongated cover being movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly, wherein when the elongated cover is in the first position the distal end of the

Art Unit: 3731

elongated cover is secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly as the elongated cover is moved from the first position to the second position (the cover can be draped and secured via 11 at any position along the surgical instrument). Guide members 72 and 73 can be considered as a cover deployment device which are between the cover and body portion(s) and which are in releasable engagement with the cover. When members 18 and 19 are released as in Figure 1 and the drawstring 11 is secured to the body portion adjacent the tool assemblies (which would be a reasonable configuration for this apparatus), the cover deployment device could be advanced along the body portion to move the cover from the first position to the second position. Regarding claims 6-8 the cover deployment sleeve half-sections 72/73 are movable to move the cover from the first position to the second position while being urged together by o-ring 11 or cover 12. Regarding claim 9, the sleeve includes a proximally located annular ring 76/77 dimensioned to facilitate movement of the sleeve between the retracted and advanced positions. Regarding claim 10, the first sleeve half-section includes at least one projection, 78 or 79 (Figure 3), and the second sleeve half-section includes at least one slot (the curved interior of 72 or 73). The projection can slide into the slot to maintain alignment between the first and second half-sections when the half-sections move outwardly (slide longitudinally relative to each other when stacked) with respect to each other. Regarding claim 11, movement of the cover deployment device from a retracted position to an advanced position can be used to invert the cover over the tool member. Regarding claim 12, the cover deployment device includes a distal

Art Unit: 3731

engagement member 78/79, a proximal guide portion 76/77 and a central body portion 74/75 interconnecting the engagement member and the guide portion. Regarding claims 14-16, a closure drawstring, 18 or 19, can close the proximal end of the cover after it has moved over the tool member. Regarding claim 17 the distal end of the cover is removably fastened to the surgical instrument by 11.

Claims 1, 2, 11 and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Jespersen (US 2003/0139767).

Regarding claims 1, 11 and 13, Jespersen disclose a surgical instrument comprising: a body portion 32; a tool assembly 34/36 supported on the distal end of the body portion; and an elongated cover 12 supported about the body portion of the instrument, the elongated cover being formed from a collapsible material and having a substantially tubular configuration (Figure 6) having open proximal and distal ends (Figure 5A), the elongated cover being movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly (Figure 7), wherein when the elongated cover is in the first position the distal end of the elongated cover is secured to the instrument adjacent to the tool assembly (Figure 5A) such that the elongated cover can be inverted about the tool assembly as the elongated cover is moved from the first position to the second position (Figure 7); and a cover deployment device at least partially disposed about the body portion, between the body portion and the cover (forceps 44, Figure 7; the forceps during normal use would engage the cover at a variety of positions, including positions which are 'about the body portion'; a portion of

Art Unit: 3731

the cover deployment device could be placed between the cover and body in order to grasp the cover from its proximal and when undeployed), the cover deployment device in releasable engagement with the cover. Regarding claim 2, the cover can be liquid impermeable (paragraph 0034). Regarding claims 14-16, the cover contains an elastic band or drawstring 52/50 for closing the proximal end of the cover after it has moved over the tool assembly (paragraph 0022; paragraph 00042). Regarding claim 17, the distal end of the cover is movably fastened to the surgical instrument (Figure 5A).

Claims 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (US 5,318,221).

Regarding claims 30-33, Green et al. disclose a surgical instrument comprising: an elongated body portion 406/329 having a first diameter and an outer surface; a stationary shell assembly **334** (Figure 17), the shell assembly having a plurality of surgical staples (col. 14, lines 4-5); a cover 327 fitted about the elongated body portion and movable from a first proximal position to a second position to cover the stationary shell assembly (col. 14, lines 10-17, "cartridge housing"). A cover deployment member 404 is positioned about the elongated body portion (Figure 17) between the elongated body portion and the cover, the cover deployment being slidable in a distal direction along the body portion (406/329 runs through 404) to move the cover to the second position because it is attached to 327 (col. 14, lines 41-42). The cover deployment member is a sleeve and is releasably attached to the cover by tabs 458 (Figure 22). In an alternate interpretation for claims 30-33, member 125/126 could be the cover deployment device for cover 127. Member 125 is positioned about and slidable along

Art Unit: 3731

body 124 (Figure 5A) and a portion of member 125 is between body 124 and cover 127 (Figure 1; at 125).

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulow et al. (US 5,665,073) in view of Williamson et al. (US 6,024,741).

Regarding claims 18-20, Bulow et al. disclose the device as disclosed above, and further disclose that the device is intended to protect the conduits of multiple surgical instruments (col. 5, lines 55-59), but do not disclose that it is usable with a linear/circular stapler or ultrasonic dissector. Williamson et al. disclose an ultrasonic cutter (col. 2, lines 1-11) circular/linear stapler (col. 3, lines 22-39) which has conduits, 30 or 19a-d. It would be obvious to one of ordinary skill in the art to combine the device of Bulow et al. with the instrument of Williamson et al. in order to protect and maintain the sterility of the conduits.

Claims 21, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jespersen (US 2003/0139767).

Regarding claim 21, Jespersen discloses a method of performing a surgical procedure comprising the following steps: providing a surgical instrument including a body portion 31, a tool assembly 34/36, a cover deployment device 44 and a cover 12 positioned about the cover deployment device, a distal end of the cover being secured about the instrument adjacent a proximal end (Figure 5A) of the tool assembly such that the cover is movable from a first position wherein the tool assembly is uncovered (Figure 5A) to a second position wherein the tool member is at least partially covered (as in Figure 7; paragraph 0044). Jespersen fails to specifically disclose placing the

Art Unit: 3731

cover deployment device on the body portion. However, it would have been obvious to one of ordinary skill in the art to have contacted the cover deployment device with the body portion in order to grasp the proximal end of the cover, where it would be obvious to one of ordinary skill in the art to use graspers with bodies sufficiently long enough so that the proximal end of the cover would rest on some portion of the body when undeployed given the enumerable body lengths for graspers that could be used with the cover and the enumerable lengths that the cover could be constructed with in order to be sufficiently sized for the great variety of surgical capturing tasks. It is not clear whether Jespersen disclosed advancing the cover deployment device along the body in order to invert the cover. However, it would have been obvious to one of ordinary skill in the art to have used the cover deployment device to pull or push the cover to the inverted state given the great variety of angles which laparoscopic instruments are constrained to interact in during a surgical procedure. Certainly, situations would arise where the space constraints are such that one of ordinary skill in the art would need to grasp the cover from the proximal end and push the cover to the inverted state; and therefore push/advance the cover deployment device along the body portion.

Jespersen further discloses: positioning the surgical instrument adjacent a surgical site and performing a surgical operation on desired tissue (Figure 5A); moving the cover from the first position to the second position by inverting the cover at least partially over the tool assembly; (as in Figure 7; paragraph 0044) and subsequently removing the surgical instrument from the surgical site (paragraph 0041) while maintaining the cover at least partially over the tool assembly (paragraph 0023; paragraph 0044). Regarding

Art Unit: 3731

claims 25 and 26, the surgical instrument includes a closure drawstring 52, and the method further includes the step of actuating the closure drawstring to close the cover at a location distally of the tool member (paragraph 0042).

Claims 18-20, 22-24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jespersen (US 2003/0139767) in view of Williamson et al. (US 6,024,741).

Regarding claims 18-20 and 22-24, Jespersen discloses the device as described above which is intended to be used with a grasping instrument but fails to disclose that the grasping instrument is a stapler or ultrasonic dissector. Williamson et al. disclose an ultrasonic cutter (col. 2, lines 1-11) and circular/linear stapler (col. 3, lines 22-39) and grasper (grasping elements 32 and 34). It would have been obvious to one of ordinary skill in the art to combine the device of Jespersen with the instrument of Williamson et al. in order to contain and remove grasped/cut tissue. Regarding claim 30, Williamson et al. disclose a stationary shell assembly 32/34 and body 30 as claimed. The cover of Jespersen would function with the stapler/grasper of Williamson et al. as depicted in Figures 5A and 7 of Jespersen. The cover deployment device 44 of Jespersen can be slid along the body of the stapler/grasper in order to invert the cover. The cover deployment device of Jespersen could be positioned about the body and a portion of the deployment device would need to go between the cover and the body in order to grasp the cover.

(10) Response to Argument

Appellant has argued on pages 9 and 10 of the brief that Bulow et al. do not disclose an elongated cover supported about the body portion of a surgical instrument. It is Examiner's position that either conduit (32, 42 and 52) can be considered as a body portion as claimed. Appellant has argued on page 10 of the brief that the cover cannot be inverted about the tool assembly as claimed because the cover is fixed to the cover deployment device 72/73. It is Examiner's position that regardless of whether the cover is fixed to the cover deployment device, the excess length of the cover would allow it to be inverted by the cover deployment device. Appellant has argued on pages 10 and 11 of the brief that the cover of Bulow et al. is not in releasable engagement with the cover deployment device. It is Examiner's position that there is no explicit disclosure of the cover being non-releasably fixed to the cover deployment device 72/73. Furthermore, the cover can be considered as being releasably engaged to the cover deployment device because it can be unfurled or released as evident when comparing Figures 3 and 5. Appellant has argued on page 14 of the brief that Jespersen does not disclose a cover deployment device at least partially disposed about the body portion between the body portion and the elongated cover as claimed. It is Examiner's position that a grasper jaw (of the cover deployment device), in any of the enumerable positions and angles which the device is clearly intended for use, would be slid under the proximal end of the cover in order to grasp the cover between the jaws. Appellant has argued throughout pages 15-17 of the brief that the cover of Green et al. is not movable to a second position to cover the stationary shell assembly. It is Examiner's position that all

Art Unit: 3731

of member 334 can be considered as a stationary shell assembly. It is a separate assembly secured at the distal end of member 324 by pins 444. Its main purpose is to house a staple cartridge 337. It is referred to as the "cartridge housing" (col. 14, lines 10-17). The claims do not require the staples to be covered. Appellant has argued on page 19 that Jespersen does not disclose or suggest a cover deployment device positioned on a body portion of a surgical instrument. It is Examiner's position that inversion of the Jespersen cover would be initiated by pushing or pulling of the cover in normal use. A second incision or portal would be needed to pull the cover over an instrument as depicted in Figure 7. However, if a single portal is used, the inverting process would need to be initiated from the proximal end of the instrument. If the surgical instrument is longer than the cover (which would be obvious if the instrument is to be manually controlled from its proximal end) and the cover tightly conforms to the instrument body (as it does in Figure 5A), then a grasper 44 jaw would need to be positioned on the surgical instrument to grab under the cover proximal end. The graspers would then need to push the cover to the inverted state. This is a completely reasonable scenario when using the Jespersen device with a single portal or incision to extract tissue.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Thomas McEvoy/
Examiner, Art Unit 3731

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